65 Clyde Road, Suite A, Somerset, NJ 08873 U.S.A.
Tel: +1-732-873-4040 ‖ Fax: +1-732-873-4043 ‖ Email: info@accessbio.net

Letter of Notification

Date: August 11, 2021

To Whom It May Concern,

This letter is to inform you regarding the performance study on the effect of the SARS-CoV-2 variants on the performance of the ***CareStart*™ COVID-19 Antigen Home Test (EUA210314), and authorized distributor brand name On/Go™ COVID-19 Antigen Self-Test**. This study was intended to evaluate the impact of the SARS-CoV-2 variants on the performance of the test.

The performance evaluation methods were *in silico* assay method, recombinant antigen method.

In conclusion, the *in silico* analysis indicates that the B.1.1.7 (UK) variant will not interfere with the performance of the *CareStart*™ COVID-19 Antigen Home Test. In addition, in-house performance evaluation using the recombinant nucleocapsid proteins of variants demonstrated the B.1.1.7 (Alpha), B.1.351 (Beta), B.1.1.248 (Gamma), B.1.617.1 (Kappa), B.1.617.2 (Delta), B.1.617.3, AY.1 (Delta plus), C.37 (Lambda) did not affect the performance of the *CareStart*™ COVID-19 Antigen Home Test.

Name: Seungjae Baek

Job Title: Head of Quality Management Division, Access Bio, Inc.

Signature: